



UHC Safety Intelligence Patient Safety Organization Annual Meeting

Case Law Updates and Implications for Member PSES Activity

December 17, 2014

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Today's Presenter



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Today's Objectives

1. Legal Landscape Update: Spotlight on Kentucky Supreme Court's decision in Tibbs v. Bunnell to prepare for similar arguments in your jurisdiction and to determine impact on PSES design.
2. Implementation Deep Dive: Options available when PSWP submitted to the PSO is needed for other reasons (e.g., peer review, state reporting)?
3. To place peer review materials under the protection of state law or the Patient Safety Act? That is the question.

Legal Landscape Update:
Spotlight on Tibbs v. Bunnell

Legal Landscape Update – Tibbs v. Bunnell

■ Background

- This is a medical malpractice action involving a 64 year old woman who died unexpectedly due to a bleeding complication at the end of an elective spine surgery at University of Kentucky Hospital (“Hospital”).
- Plaintiff’s estate filed action against three Hospital employed surgeons.
- Plaintiff requested copies of any post-incident event reports regarding patient’s care.
- Defendants moved for a protective order arguing that the report had been created and collected through UK Health Care’s PSES and reported to its PSO, the UHC Performance Improvement PSO, and therefore was PSWP and not subject to discovery.

Legal Landscape Update – Tibbs v. Bunnell (cont'd)

- Trial court held that the report was not PSWP under the Patient Safety Act (“PSA”) because it did not fall within the statutory definition.
- UK filed a Writ of Prohibition with the Appellate Court to prevent trial court from requiring production of the report.
- Appellate Court Decision
 - Appellate Court granted the Writ.
 - In its opinion, the Court correctly ruled that the PSA pre-empted state law that otherwise would not have protected the report from discovery.
 - Under its interpretation of the scope of PSA protection, however, the Court held that the privilege only applies to documents that contain “self-examining analysis.”

Legal Landscape Update – Tibbs v. Bunnell (cont'd)

- In other words, the only documents subject to protection are those reports created by the treating physician, nurse or other caregivers, which analyzes their own actions.
- Because this decision erroneously narrowed the PSA protections to a very limited set of materials, UK again filed a Writ of Prohibition to the Supreme Court of Kentucky as a matter of right.
- Supreme Court Decision
 - Court granted the Writ and the case was assigned to a judge in February, 2013.
 - Decision was issued on August 21, 2014, 18 months later in a divided 4-2 opinion.

Legal Landscape Update – Tibbs v. Bunnell (cont'd)

- Court reversed the Appellate Court’s narrow construction of the PSA protections as being contrary to the clear intent of Congress which was to:

“encourage health care providers to voluntarily associate and communicate [PSWP] among themselves through in-house [PSES] and with and through affiliated [PSOs] in order to hopefully create an enduring national system capable of studying, analyzing, disseminating and acting on events, solutions, and recommendations for the betterment of national patient safety, healthcare quality, and healthcare outcomes” (Opinion at p. 5) (also citing to Walgreens case)

Legal Landscape Update – Tibbs v. Bunnell (cont'd)

- The Court, however, went on to rule that reports, analyses and documents that hospitals are required to establish, maintain and utilize “as necessary to guide the operation, measure of productivity and reflect the program of the facility” must be collected outside of the PSES and therefore cannot be protected under the PSA.
- Because the incident report in question fell into this category of documents required to be “established, maintained and utilized” under state law, the Court held it was subject to discovery.
- Based on this statutory construction analysis, the Court ordered that the matter be remanded to the trial court for an in camera review to determine what aspects, if any, of the report are privileged and not subject to discovery and what information must be produced.

Legal Landscape Update – Tibbs v. Bunnell (cont'd)

- UK has since filed a Motion and Petition for Rehearing for the purpose of remanding the case back to the Appellate Court because the statutory construction argument was never presented to the trial and Appellate Court and therefore was never addressed by the parties.
- This Petition was supported in separate motions by the UHC Safety Intelligence PSO, the AHA, AMA, The Joint Commission and over 30 other amicus parties along with additional arguments as to how the Court erred. These arguments included the following:
 - Court did not correctly interpret Congress's intent as to the full scope of the PSA's protections.

Legal Landscape Update – Tibbs v. Bunnell (cont'd)

- PSA does not preclude a hospital from collecting and maintaining incident reports within its PSES unless required to submit these reports to the state or federal government.
- Court glossed over the fact that Kentucky does not require these incident reports to be reported to the state.
- While information collected outside the PSES cannot be protected, the report in question clearly was collected and maintained in UK's PSES.
- The fact that a State mandated the establishment, collection and maintenance of a record does not automatically mean it cannot be accomplished within a PSES – it can be dropped out later and reported to the State if required.

Legal Landscape Update – Tibbs v. Bunnell (cont'd)

- Even if a mandated report was incorrectly reported to a PSO, the hospital cannot disclose unless it specifically authorizes disclosure consistent with the PSA requirements.
- If not disclosed, the hospital runs the risk of being cited, fined or otherwise penalized unless it can otherwise demonstrate compliance with state/federal laws.
 - Neither CMS nor TJC requires a PSO or provider to turn over PSWP.

Legal Landscape Update – Tibbs v. Bunnell (cont'd)

- Amicus motions in support of Petition for Rehearing were denied but UK's Petition is still pending and a ruling is expected within the next 2 to 4 months.
- If a Rehearing is granted, a revised decision could take another year before it is issued.
- What Legal Impact Does Tibbs Have?
 - Decision is not final until Petition for Rehearing is resolved – decision could be affirmed without change if the Petition is denied or it could be modified.
 - Even if decision is not modified, it is only binding on courts, PSO's, and providers located in Kentucky and no other state.

Legal Landscape Update – Tibbs v. Bunnell (cont'd)

- There are still procedural issues and potential discovery disputes being played out in the Tibbs case and therefore the final outcome on what information ultimately needs to be produced has not been determined.
- One issue that has been raised is whether AHRQ/OCR would fine UK if it turned over the report – could serve as a vehicle to get into federal court because there would be a state court decision which conflicts with a federal statute and potential agency action against the PSO and/or provider.
- A concern is that the wrong analysis in Tibbs could be embraced by other courts looking for a way to limit the PSA protections, but keep in mind trial court decisions in other jurisdictions are only binding on the parties involved in the litigation

Legal Landscape Update – Tibbs v. Bunnell (cont'd)

- Should PSOs/Hospitals limit scope of what to collect in their PSES consistent with Tibbs decision?
 - No!
 - These issues/disputes will be decided on a state by state basis. The only binding decisions in your state affecting state, versus federal, claims are decisions issued by the State supreme court or the appellate courts – not the trial courts.
- Reminders
 - In a state with mandated reporting requirements you should only provide what is minimally necessary – limit reports to the facts if permitted.

Legal Landscape Update – Tibbs v. Bunnell (cont'd)

- What you are not required to report to the state (or federal government) can be collected in your PSES and reported to the PSO.
- To protect against a Tibbs analysis consider re-titling reports. In other words, the patient incident report you may be required to collect and maintain under state law can be limited to the facts and the impressions, reviews and assessments can be included in a separate “quality assessment report” or “occurrence report”, collected in your PSES and reported to the PSO.

Implementation Deep Dive:
Options Available When PSWP is
Needed for Other Reasons

Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons

■ Hypothetical

- Dr. Smith performed wrong site surgery on a 50 year old patient who had commercial insurance.
- Hospital and Dr. Smith did not bill for the surgery or in-patient stay but patient complained to State Department of Public Health.
- State has a mandated adverse event reporting requirement for wrong site surgery but does not require that the hospital conduct or report any subsequent root cause analysis.
- Hospital submitted its mandated report but also performed both an RCA and a peer review analysis because this was Dr. Smith's second wrong site surgery in 6 months.
- RCAs and peer review analyses are collected within the hospital's PSES.
- Department of Public Health shows up at the hospital to investigate patient complaint and demands to see RCA and peer review analysis.

Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

- Retroactive Look: Information has already been reported to the PSO, but now is needed for other uses
- What are my options?
 - Option 1 – Consider Valid Authorized Disclosure
 - Option 2 -- Refuse to Authorize Disclosure

Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

- Option 1 – Information Already Reported: Consider Valid Authorized Disclosure
 - Under Section 3.206(a)(3) identifiable patient safety work product can be disclosed with a valid authorization from each provider identified in the work product prior to disclosure. Authorization must:
 - Be in writing and signed by the provider from whom authorization is sought.
 - Contain sufficient detail to fairly inform provider of nature and form of disclosure.
 - Authorization must be retained by disclosing entity for six (6) years from the date of the last disclosure and made available to HHS Secretary.

Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

- Here, hospital and Dr. Smith would each need to sign a valid authorization if both names were being provided.
 - Might be able to avoid disclosing Dr. Smith's name and identity.
- Disclosure does not constitute a waiver of the PSA protections.

Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

- Option 2 – Information Already Reported: Refuse to Authorize Disclosure
 - There may be reasons for not wanting to provide a valid authorization, especially if the information is sensitive and/or your State confidentiality and privilege statute would not apply as back-up protection.
 - CMS and TJC have taken the position that they will not demand production of PSWP.
 - Remember that the PSA allows for a voluntary disclosure to accrediting bodies but identifiers have to be removed (Section 3.206(b)(8)).

Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

- If not disclosing, you need to be prepared to otherwise demonstrate compliance with state/federal/accreditation laws and standards, whichever are applicable.
- Remember, however, that any analysis and deliberation conducted in PSES is automatically considered PSWP even if not reported.

Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

- Prospective Look: Information not yet reported to the PSO, but needed for other uses
- What are my options?
 - Option 3 – Collect and Hold in PSES but use Drop Out Provision
 - Option 4 – Disclose and Send Copies to PSO

Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

- Option 3 – Collect and Hold in PSES but Drop Out
 - Hospitals generally have a good sense as to when certain adverse events are going to trigger a patient complaint, lawsuit or a government or other third party investigation.
 - Hospitals have the option of collecting an RCA and peer review analysis and not reporting it, either physically or functionally, in case they want to be able to drop it out of the PSES and disclose.
 - The information is still protected while it is being held on the PSES.
 - Once it is dropped out it cannot later be reported to the PSO and therefore cannot be treated as PSWP.
 - Must document removal from PSES.

Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

- Information might be protected, however, under State confidentiality and privilege statutes – need to check statute and consult with legal counsel.
- If information is never requested and not dropped out you can then report to PSO.
- Should incorporate into your PSES or through other documentation why the information is being held and not reported within your usual time frames.

Implementation Deep Dive: Options Available When PSWP is Needed for Other Reasons (cont'd)

- Option 4 – Disclose and Send Copies to PSO
 - PSA allows you to send copies of ineligible information, i.e., mandated reports or information that has been dropped out, to the PSO.
 - Copies will be considered PSWP.
 - In terms of whether the materials you have reported or dropped out are otherwise discoverable will depend on whether there is an alternative federal and/or state confidentiality/privilege statute available.

To Place Peer Review Materials Under the
Protection of State Law or the Patient Safety Act?

That is the Question

State Versus PSA Peer Review Protections

- Comparative Factors to Consider
 - Scope of protected activities and oral/written reports and other documents.
 - Scope of protected entities, i.e., hospital, physicians, nursing home.
 - Is there mandated state reporting requirements and is reported information protected under State law and/or FOIA?
 - Can the protections be waived?
 - Will State protections apply in federal court with respect to federal claims, i.e., antitrust discrimination?
 - Is there established case law?

State Versus PSA Peer Review Protections

(cont'd)

- State Law
 - See Attachment A for a summary of peer review statutes in Illinois, Missouri and North Carolina.
- Patient Safety Act
 - The confidentiality and privilege protections afforded under the PSA generally apply to reports, minutes, analyses, data, discussions, recommendations, etc., that relate to patient safety and quality activities if generated, managed, or analyzed within the PSES and collected for reporting to a PSO.
 - Any licensed provider, i.e., physician, physician group, surgicenters, clinic, hospital, nursing home, home health facility, etc., can be covered under the PSA whereas in many states the kinds of providers that can be protected is more limited.

State Versus PSA Peer Review Protections

(cont'd)

- The scope of what activities and information can be protected under the PSA, generally speaking, is broader than under state law.
- Any licensed provider in the state, i.e., physician, physician group, surgicenters, clinic, hospital, nursing home, home health facility, etc., or entity authorized to provide health care services can be covered under the PSA.
- The protections apply in both state and, for the first time, federal proceedings.
- The protections can never be waived.
- If the protections are greater than those offered under state law the PSA pre-empts state law.

State Versus PSA Peer Review Protections

(cont'd)

- PSWP is not admissible into evidence nor is it subject to discovery.
- Key to these protections is the design of the provider's and PSO's patient safety evaluation system ("PSES").

Attachment A

- Summary of Peer Review Statutes in North Carolina, Missouri and Illinois

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? – North Carolina

- North Carolina
 - N.C. Gen. Stat. § 131E-95(B)
 - Proceedings of a medical review committee, the records and materials it produces and the materials it considers shall be confidential and not subject to discovery or introduction into evidence in any civil action against a hospital, surgicenter or provider of health services which results from matters which are subject to evaluation and review by the committee.
 - If information is otherwise available, it cannot be protected.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? – North Carolina (cont'd)

- Information can be disclosed to a professional standards review organization, such as The Joint Commission, or to a PSO or its designated contractors.
- Minimum necessary standard applies.
- Protections arguably apply to peer review conducted in a physician group, but no case law on this question.
- Can be sent to a PSO and still be kept confidential.
- Appears that protections could be waived if information is disclosed outside of peer review process.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? – North Carolina (cont'd)

- One court held that protections do apply in federal proceedings.
- Not clear if information can be shared throughout system.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? - Missouri

- Missouri
 - Missouri Revised Statutes, Chapter 537, Section 537.035
 - “Peer Review Committee” is a committee of health care professionals (physician, surgeon, dentist, podiatrist, pharmacist, psychologist, nurse, social worker, professional counselor or mental health professional) with the responsibility to evaluate, maintain, or monitor the quality and utilization of health care services or to exercise any combination of such responsibilities.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? - Missouri (cont'd)

- Entities covered include committees of:
 - Health care professional societies
 - Professional corporation of health care professionals
 - Health care professionals employed by or affiliated with a university
 - Licensed hospitals or other health care facilities, including long term care
 - Organizations formed pursuant to state or federal law to exercise responsibilities of a peer review committee
 - HMOs

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? - Missouri (cont'd)

- Interviews, memorandums, proceedings, findings, deliberations, reports and minutes concerning the health care provided any patient are not subject to discovery and is not admissible into evidence in any judicial or administrative action for failure to provide appropriate care.
- Persons in attendance cannot be required to disclose or testify.
- Information is discoverable if otherwise available.
- Can be required to testify as to personal knowledge.
- Protections cannot be waived.
- Protections do not apply in peer review litigation.
- Not clear whether the state protections would apply where plaintiff brings a federal cause of action in federal court, i.e., antitrust, discrimination.
- Not clear as to whether information can be freely shared throughout the system.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? - Illinois

- Illinois
 - 735 ILCS 5/8-2101
 - All information, interviews, reports, statements, memoranda, recommendations, letters of reference or other third party confidential assessments of a health care practitioner's professional competence, or other data.
 - Allied medical societies, health maintenance organizations, medical organizations under contract with health maintenance organizations or with insurance or other health care delivery entities or facilities.
 - Their agents, committees of ambulatory surgical treatment centers or post-surgical recovery centers or their medical staffs, or committees of licensed or accredited hospitals or their medical staffs.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? - Illinois (cont'd)

- Including Patient Care Audit Committees, Medical Care Evaluation Committees, Utilization Review committees, Credential Committees and Executive Committees,, or their designees (but not the medical records pertaining to the patient), used in the course of internal quality control or of medical study for the purpose of reducing morbidity or mortality, or for improving patient care or increasing organ and tissue donation.
- Shall be privileged, strictly confidential and shall be used only for medical research, the evaluation and improvement of quality care, or granting, limiting or revoking staff privileges or agreements for services.
- Information can be used in disciplinary hearings and subsequent judicial review.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? - Illinois (cont'd)

- Protections have been interpreted fairly broadly but information produced for a different purpose, i.e., risk management, is not protected even if used by a peer review committee.
- Although the Medical Studies Act references “medical organizations” under contract with HMOs or other healthcare delivery entities or facilities, surgicenters and hospitals, Appellate Courts have not extended protections to nursing homes or pharmacies.

How do state confidentiality/privilege protections compare to those offered under the Patient Safety Act? - Illinois (cont'd)

- Protections cannot be waived if used for statutory purposes.
- Information arguably can be shared throughout the system among controlled affiliates subject to physician authorization.
- Protections do not apply to federal claims brought in federal court.